



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0824]

Regulatory Site Visit Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) is announcing an invitation for participation in its Regulatory Site Visit Training Program (RSVP). This training program is intended to give CBER regulatory review, compliance, and other relevant staff an opportunity to visit biologics facilities. These visits are intended to allow CBER staff to directly observe routine manufacturing practices and to give CBER staff a better understanding of the biologics industry, including its challenges and operations. The purpose of this document is to invite biologics facilities to contact CBER for more information if they are interested in participating in this program.

DATES: Submit either an electronic or written request for participation in this program by

[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL

REGISTER]. The request should include a description of your facility relative to products regulated by CBER. Please specify the physical address(es) of the site(s) you are offering.

ADDRESSES: If your biologics facility is interested in offering a site visit, submit either an electronic request to <http://www.regulations.gov> or a written request to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. If you previously responded to earlier requests to participate in this

program and you continue to be interested in participating, please renew your request through a submission to the Division of Dockets Management.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Henderson,
Division of Manufacturers Assistance and Training,
Center for Biologics Evaluation and Research (HFM-49),
Food and Drug Administration,
1401 Rockville Pike, suite 200N,
Rockville, MD 20852-1448,
301-827-2000, FAX: 301-827-3079,
email: industry.biologics@fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products including blood and blood products, vaccines, and cellular, tissue, and gene therapies. CBER is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness, and availability of biological products to patients. To support this primary goal, CBER has initiated various training and development programs, including programs to further enhance performance of its compliance staff, regulatory review staff, and other relevant staff. CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing CBER staff with a better understanding of the biologics industry and its operations. Further, CBER seeks to enhance: (1) Its understanding of current industry practices and regulatory impacts and needs and (2) communication between CBER staff and

industry. CBER initiated its RSVP in 2005. Through these annual notices, CBER is requesting that those firms that have previously applied and are still interested in participating reaffirm their interest. CBER is also requesting that new interested parties apply.

II. RSVP

A. Regulatory Site Visits

In this program, over a period of time to be agreed upon with the facility, small groups of CBER staff may observe operations of biologics establishments, including for example, blood and tissue establishments. The visits may include the following: (1) Packaging facilities, (2) quality control and pathology/toxicology laboratories, and (3) regulatory affairs operations. These visits, or any part of the program, are not intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but are meant to improve mutual understanding and to provide an avenue for open dialogue between the biologics industry and CBER.

B. Site Selection

CBER will be responsible for all travel expenses associated with the site visits. Therefore, selection of potential facilities will be based on the coordination of CBER's priorities for staff training as well as the limited available resources for this program. In addition to logistical and other resource factors to consider, a key element of site selection is a successful compliance record with FDA or another Agency with which we have a memorandum of understanding. If a site visit also involves a visit to a separate physical location of another firm under contract to the applicant, the other firm also needs to agree to participate in the program, as well as have a satisfactory compliance history.

III. Requests for Participation

Identify requests for participation with the docket number found in the brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 30, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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